

## **CLAIMS:**

The following is a listing of all claims in the application with their status and the text of all active claims.

### **Claims 1-13 (CANCELED)**

14. **(WITHDRAWN)** The pharmaceutical composition of claim 1 wherein the component A is a biguanide the component B is an ACE inhibitor and the component C is Aspirin
15. **(WITHDRAWN)** The pharmaceutical composition of claim 1 wherein the component A is a biguanide the component B is Aspirin and the component C is an ACE inhibitor.
16. **(WITHDRAWN)** The pharmaceutical composition as defined in claim 14 wherein the component A is a metformin the component B is Aspirin and the component C is Ramipril.
17. **(WITHDRAWN)** A pharmaceutical kit containing the agents as defined in claim 16 either as single or dual or as triple entities for administration to humans suffering from diabetes and its associated disorders.
18. **(WITHDRAWN)** A pharmaceutical kit containing the agents as defined in claim 16 either as single or dual or triple entities for administration to humans suffering from cardiovascular and its associated disorders with or without diabetes.
19. **(WITHDRAWN)** A pharmaceutical kit as defined in claim 16 wherein the agents are consumed within 0-12 hours after ingestion of any of the other two therapeutic agents.
20. **(WITHDRAWN)** A method of treatment using a pharmaceutical composition as defined in claim 16 which when ingested by human
  - a) Reduces the Cmax by at least 10-15 % for the slow release component relative to the corresponding immediate release component.
  - b) Increases the Tmax by at least about 20-30 % for the slow release component relative to

the corresponding immediate release component.

c) While having an insubstantial effect on the area under the plasma concentration time curve (AUC) of the dose of the slow release component relative to the corresponding immediate release component.

21. **(WITHDRAWN)** A therapeutically effective amount of a pharmaceutical composition of claim 16 which allows a reduction in the dosing regimen of any of the individual agents for diabetic and its associated disorders.
22. **(WITHDRAWN)** A therapeutically effective amount of a pharmaceutical composition of claim 16 which allows a reduction in the dosing regimen of any of the individual agents for cardiovascular and its associated disorders.
23. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 16 in the form of one or more tablets.
24. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 16 in the form of one or more capsules.
25. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 16 in the form of one or more tablets and /or capsules.
26. **(WITHDRAWN)** The pharmaceutical composition of claim 16 wherein when tested for in-vitro release, around 30-50% of the drug is released for the slow release component within a period of about 2 to 3 hours and not less than 75% of the drug is released within a period maximum 24 hours.
27. **(WITHDRAWN)** A method of treating a disease with a pharmaceutical composition of claim 16 comprising administering a human in need of treatment for the said disease.
28. **(WITHDRAWN)** The pharmaceutical composition of claim 1 wherein the component A is a nitrate the component B is platelet inhibitor and the component C is an HMG-CoA inhibitor
29. **(WITHDRAWN)** The pharmaceutical composition of claim 28 wherein the component A is isosorbide mononitrate the component B is clopidogrel / aspirin and the component C is statin.

30. **(WITHDRAWN)** A pharmaceutical kit containing the agents as defined in claim 28 either as single or dual or triple entities for administration to humans suffering from hypertensive and its associated disorders.
31. **(WITHDRAWN)** A pharmaceutical kit containing the agents as defined in claim 28 either as a single or dual or triple entities for administration to humans suffering from cardiovascular and its associated disorders.
32. **(WITHDRAWN)** A pharmaceutical kit containing the agents as defined in claim 28 either as a single or dual or triple entities for administration to humans suffering from hyperlipidemia and its associated disorders.
33. **(WITHDRAWN)** A pharmaceutical kit as defined in claim 28 wherein the agents are consumed within 0-12 hours after ingestion of any of the other two therapeutic agents.
34. **(WITHDRAWN)** The pharmaceutical composition as defined in claim 28 which when ingested by human
- a) reduces the C<sub>max</sub> by at least 10-15 % for the slow release component relative to the corresponding immediate release component
  - b) increases the T<sub>max</sub> by at least about 20-30 % for the slow release components relative to the corresponding immediate release component
  - c) while having an insubstantial effect on the area under the plasma concentration time curve (AUC) of the dose of the slow release component relative to the corresponding immediate release component.
35. **(WITHDRAWN)** A therapeutically effective amount of a pharmaceutical formulation of claim 28 which allows a reduction in the dosing regimen of any one of the individual agents for patients with hypertension and its associated disorders.
36. **(WITHDRAWN)** A therapeutically effective amount of a pharmaceutical formulation of claim 28 which allows a reduction in the dosing regimen of any one of the individual agents for patients with cardiovascular and its associated disorders.

37. **(WITHDRAWN)** A therapeutically effective amount of a pharmaceutical formulation of claim 28 which allows a reduction in the dosing regimen of any one of the individual agents for patients with hyperlipidemic and its associated disorders
38. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 28 in the form of one or more tablets.
39. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 28 in the form of one or more capsules.
40. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 28 in the form of one or more tablets and /or capsules.
41. **(WITHDRAWN)** The pharmaceutical composition as defined in claim 28 wherein when tested for in-vitro release, around 30-50% of the drug is released for the slow release component within a period of about 2 to 3 hours and not less than 75% of the drug is released within a period maximum 24 hours.
42. **(WITHDRAWN)** A method of treating a disease with a pharmaceutical composition of claim 28 comprising administering a human in need of treatment for the said disease.
43. **(WITHDRAWN)** The pharmaceutical composition of claim 1 wherein the component A is a calcium channel blocker, the component B is beta-blocker and the component C is an HMG-CoA inhibitor
44. **(WITHDRAWN)** The pharmaceutical composition as defined in claim 43 wherein the component A belongs to 1,4-dihydropyridines, the component B is beta blocker and the component C is a statin.
45. **(WITHDRAWN)** The pharmaceutical composition as defined in claim 43 wherein the component A is Nifedipine, the component B is atenolol and the component C is atorvastatin.

46. **(WITHDRAWN)** A pharmaceutical kit containing the agents as defined in claim 43 either as single or dual or triple entities for administration to humans suffering from cardiovascular and its associated disorders.
47. **(WITHDRAWN)** A pharmaceutical kit containing the agents as defined in claim 43 either as single or dual or triple entities for administration to humans suffering from hyperlipidemic and its associated disorders.
48. **(WITHDRAWN)** A pharmaceutical kit as defined in claim 43 wherein the agents are consumed within 0-12 hours after ingestion of any of the other two therapeutic agents.
49. **(WITHDRAWN)** The pharmaceutical composition as defined in claim 43 which when ingested by human
- a) reduces the C<sub>max</sub> by at least 10-15 % for the slow release component relative to the corresponding immediate release component
  - b) increases the T<sub>max</sub> by at least about 20-30 % for the slow release component relative to the corresponding immediate release component
  - c) while having an insubstantial effect on the area under the plasma concentration time curve (AUC) of the dose of the slow release component relative to the corresponding immediate release component.
50. **(WITHDRAWN)** A therapeutically effective amount of a pharmaceutical formulation of claim 43 which allows a reduction in the dosing regimen of any one of the individual agents for patients with cardiovascular and its associated disorders.
51. **(WITHDRAWN)** A therapeutically effective amount of a pharmaceutical formulation of claim 43 which allows a reduction in the dosing regimen of any one of the individual agents for patients with hyperlipidemic and its associated disorders.
52. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 43 in the form of one or more tablets.

53. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 43 in the form of one or more capsules.
54. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 43 in the form of one or more tablets and /or capsules.
55. **(WITHDRAWN)** The pharmaceutical composition as defined in claim 43 wherein when tested for in-vitro release, around 30-50% of the drug is released for the slow release component within a period of about 2 to 3 hours and not less than 75% of the drug is released within a period maximum 24 hours.
56. **(WITHDRAWN)** A method of treating a disease with a pharmaceutical composition of claim 43 comprising administering a human in need of treatment for the said disease.
57. **(WITHDRAWN)** The pharmaceutical composition of claim 1 wherein the component A is a calcium channel blocker, component B is an angiotensin receptor antagonist and the component C is an HMG-CoA inhibitor
58. **(WITHDRAWN)** The pharmaceutical composition as defined in claim 57 wherein the component A is a 1,4 dihydropyridine, the component B is a sartan and the component C is a statin.
59. **(WITHDRAWN)** The pharmaceutical composition as defined in claim 57 wherein the component A is a Nifedipine, the component B is losartan and the component C is atorvastatin.
60. **(WITHDRAWN)** A pharmaceutical kit containing the agents as defined in claim 57 either as single or dual or triple entities for administration to humans suffering from hypertension and its associated disorders.
61. **(WITHDRAWN)** A pharmaceutical kit containing the agents as defined in claim 57 either as single or dual or triple entities for administration to humans suffering from cardiovascular and its associated disorders.
62. **(WITHDRAWN)** A pharmaceutical kit containing the agents as defined in claim 57 either as single or dual or triple entities for administration to humans suffering from hyperlipidemic and its associated disorders.

63. **(WITHDRAWN)** A pharmaceutical kit as defined in claim 57 wherein the agents are consumed within 0-12 hours after ingestion of any of the other two therapeutic agents.
64. **(WITHDRAWN)** The pharmaceutical composition as defined in claim 57 which when ingested by human
- a) reduces the C<sub>max</sub> by at least 10-15 % for the slow release component relative to the corresponding immediate release component.
  - b) increases the T<sub>max</sub> by at least about 20-30 % for the slow release component relative to the corresponding immediate release component
  - c) while having an insubstantial effect on the area under the plasma concentration time curve (AUC) of the dose of the sustained / controlled / extended release components relative to the corresponding immediate release component.
65. **(WITHDRAWN)** A therapeutically effective amount of a pharmaceutical formulation of claim 57 which allows a reduction in the dosing regimen of any one of the individual agents for patients with hypertension and its associated disorders.
66. **(WITHDRAWN)** A therapeutically effective amount of a pharmaceutical formulation of claim 57 which allows a reduction in the dosing regimen of any one of the individual agents for patients with cardiovascular and its associated disorders.
67. **(WITHDRAWN)** A therapeutically effective amount of a pharmaceutical formulation of claim 57 which allows a reduction in the dosing regimen of any one of the individual agents for patients with hyperlipidemic and its associated disorders.
68. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 57 in the form of one or more tablets.
69. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 57 in the form of one or more capsules.

70. **(WITHDRAWN)** The pharmaceutical formulation as defined in claim 57 in the form of one or more tablets and / or capsules.

73. **(CURRENTLY AMENDED)** An oral delivery system comprising combination of

- a) a slow release component comprising biguanide and a hydrophilic and/or at least one or more hydrophobic polymers and/or at least one or more hydrophobic materials,
- b) a slow release or immediate release component comprising sulfonylurea and for slow release, a hydrophilic and/or at least one or more hydrophobic polymers and/or at least one or more hydrophobic materials,
- c) an immediate release component comprising glitazone,

wherein, the delivery system ~~is a fixed dose combination for the treatment of diabetes and its associated disorders~~ released around 30-50% of the slow release component within a period of about 2 to 3 hours and not less than 75% of the slow release component within a period of about 24 hours, characterized in that the delivery system is a fixed dose combination for the treatment of diabetes and its associated disorders.

74. **(PREVIOUSLY PRESENTED)** The delivery system of claim 73, wherein the hydrophilic polymers comprises one or more of hydroxypropylmethylcellulose, hydroxypropylcellulose, sodium carboxymethylcellulose, carboxymethylcellulose calcium, ammonium alginate, sodium alginate, potassium alginate, calcium alginate, propylene glycol alginate, alginic acid, polyvinyl alcohol, povidone, carbomer, potassium pectate and potassium pectinate.

75. **(PREVIOUSLY PRESENTED)** The delivery system of claim 73, wherein hydrophobic polymers comprises one or more of ethyl cellulose, hydroxyethylcellulose, ammonio methacrylate copolymer, methacrylic acid copolymers, methacrylic acid-acrylic acid ethyl ester copolymer, methacrylic acid esters neutral copolymer,



dimethylaminoethylmethacrylate-methacrylic acid esters copolymer, vinyl methyl ether/maleic anhydride copolymers, their salts and esters.

**76. (PREVIOUSLY PRESENTED)** The delivery system of claim 73, wherein the hydrophobic materials comprises one or more of beeswax, carnauba wax, microcrystalline wax, and ozokerite; fatty alcohols such as cetostearyl alcohol, stearyl alcohol; cetyl alcohol myristyl alcohol etc; and fatty acid esters such as glyceryl monostearate, glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax, glyceryl palmitostearate, glyceryl behenate, and hydrogenated castor oil.

**77. (PREVIOUSLY PRESENTED)** The delivery system of claim 73, wherein the slow release formulation include a mixture of at least a hydrophilic and at least a hydrophobic polymer in the range form 0.05:1 to 19:1.

**78. (PREVIOUSLY PRESENTED)** The delivery system of claim 73, wherein the slow release component of (a) is present from 10-90% w/w.

**79. (PREVIOUSLY PRESENTED)** The delivery system of claim 73, wherein the slow release component (b) is present from 0.25-10%w/w or immediate release component (b) is present from 0.025-0.5%w/w.

**80. (PREVIOUSLY PRESENTED)** The delivery system of claim 73, wherein the immediate release component (c) is present from 0.25-5% w/w.

**81. (PREVIOUSLY PRESENTED)** The delivery system of claim 73, wherein the delivery system provides release of slow release component by gastro retentive mechanism.